pdSTIM™

Are you or your loved one having a hard time weaning off the ventilator after 4 or more days?

We are currently seeking patients to take part in a voluntary research study!

The purpose of the study is to see if the pdSTIM™ system is safe and effective for helping to get patients that are on a breathing machine (mechanical ventilator) off the machine more quickly than regular care without the system.

Potential Benefits of the pdSTIM System may include the following:

- Reduced time on mechanical ventilation
- Reduced time in the Intensive Care Unit
- Increased strength of the main breathing muscle, the diaphragm

There are possible risks related to the study device and procedures that will be discussed with your care team.
It is possible that you or your loved one may not benefit from being in this study.

How does the pdSTIM™ System work?

The pdSTIM System uses small wires placed under a muscle on each side of the neck. The wires are connected to a box that controls electrical pulses that stimulate the phrenic nerves. These nerves are connected to the main breathing muscle, the diaphragm. Early research has shown that this therapy shows potential to strengthen the diaphragm, which could help to remove someone from the ventilator more quickly than standard care.

Not all subjects in the study will receive the pdSTIM system. The pdSTIM System is "investigational". In other words, it is not yet approved by the FDA to be used. There is a 50/50 chance that you or your loved one will receive it. If they do receive it, they will have two therapy sessions each day where the nerves will be activated, and the diaphragm is exercised. Each session will last two hours. This will continue until you or your loved one are removed from the ventilator or for up to 30 days, whichever is less.

For more information, go to stimdia.com/clinical-study

CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use.